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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,852	01/17/2002	Michael Neal Blackburn	P50438D2	2915

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,852	BLACKBURN ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1, 2, 6, 7, 10, 39-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 2, 6, 10, 39-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/17/02 + 9/26/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 1-17-02 has been entered into the record. Claims 1, 2, 6, 7, 10 and 39-43 are pending and under examination.

Priority

The current status of all nonprovisional parent applications referenced in the first line of the specification should be updated.

Information Disclosure Statement

The information disclosure statements filed 1-17-02 and 9-26-03 have been considered. A initialed copy is enclosed.

Double Patenting

Claims 1, 2, 6, 7, 10 and 39-43 of this application conflict with claims 1-12 of Application No. 10/430,176. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn

to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 6 and 7 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 6, 7 and 8, of copending Application No.10/430,176. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. It is noted that the identical antibodies are used to inhibit thrombosis and therefore the function of "having long-lasting protective activity in the '176 application is inherent to the antibodies. As such, these applications are claiming the same invention.

Claims 1, 6 and 7 are directed to the same invention as that of claims 6-8 of commonly assigned 10/430,176. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 10 and 39-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 5-8 and 12 of copending Application No. 10/430,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species recited in the '176 anticipates the instant genus claims recited herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 6, 7, 10, and 39-43 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6, 7, 10 and 39-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As to claim 1 and every claim dependent thereon (2, 6, 7, 10 and 39-43), the specification as filed only provides for conception of the combination of administering in an effective does of an anti-coagulation factor IX/IXa monoclonal antibody having self-limiting neutralizing activity. The specification does not provide written description support for the genus claim now recited. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v.

American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In In re East and Harmon (CCPA) 181 USPQ 716 (May 9, 1994) a similar issue was presented to the courts who decide that the claims of a reissue application were drawn to new matter since they broadly recite genus of "carrier particles" which is not disclosed in original patent, which discloses only subgenus of "magnetic carrier particles" and species of "iron, ferrites, nickel, and cobalt" carrier particles. In the instant case the genus of anti-coagulation factor IX/IXa monoclonal antibody does not find conception by way of written description in the application as filed.

As to claim 41, there is no conception of a subgenus of monoclonal antibodies that bind Factor IX gla domain. The specification at page 60, teaches that the BC2 antibody binds to an epitope contained within residues 3-11 of the Factor IX gla domain. The newly recited subgenus of binding any portion of Factor IX gla domain lacks conception as filed in this application. It cannot be said that a subgenus is necessarily described by a genus encompassing it (i.e. the instant anti-coagulation factor IX/IXa monoclonal antibody) and a species upon which it reads (i.e. murine monoclonal antibody BC2). In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b). Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

As to claim 42, there is no conception antibody epitopes that is located within residues 3-11 of Factor IX. The specification at page 60, teaches that the BC2 antibody binds to an epitope contained within residues 3-11 of the Factor IX gla domain. The newly recited subgenus of binding residues 3-11 of Factor IX is not the same as residues 3-11 of the Factor IX gla domain. There is no contemplation or written description of residues 3-11 of Factor IX. The passage specifically recites residues 3-11 of a particular domain and not the native Factor IX. As such,

this new language provides for a new subgenus that lacks conception in this application.

As to claim 43, it is not apparent that this limitation "wherein the antibody has a binding affinity of at least 4 nM" resides in the specification as filed. This issue is best resolved by Applicants pointing to the specification by specific page and line number where written description support can be found.

Claims 1, 2, 6, 7, 10 and 39-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and every claim dependent thereon, the claim is confusing in regard to the language anti-coagulation factor IX/IXa monoclonal antibody because it is unclear whether the antibody binds factor IX, Factor IXa or both. Clarification is respectively requested.

As to claim 1 and every claim dependent thereon, the phrase "effective dose" renders the claim indefinite because it is not clear from the claim construction what effect is achieved by the amount.

As to claims 6 and 7, the claims re rendered indefinite from the use of the term "... the monoclonal antibody has the identifying characteristics of..." because it is unclear what identifying characteristics of the recited monoclonal antibodies are being particular claimed. This rejection may be obviated by reciting "...the monoclonal antibody having all the characteristics of .." Should Applicants amendment the claims as recited, a deposit for patent purposes will be required because, the particular antibodies will be required to determine if the antibodies have all of the identifying characteristics as compared with the particularly referenced monoclonal antibodies.

As to claim 41, the claim recites "an epitope of the Factor IX gla domain". The specification fails to set forth epitopes of the Factor IX gla domain and fails to teach the metes and bounds of the Factor IX gla domain.

As to claim 42, the claim recites "wherein the epitope is locate within residues 3-11 of Factor IX." However, this language is indefinite because recitation of specific residues in the absence of the corresponding sequence does not allow the skilled artisan to be readily apprised of the metes and bounds of the specific residues recited. It is noted that Factor IX has a pre-pro region and it is further unclear as to which Factor IX is referenced, pre-pro form of Factor IX or the processed form. As such, clearly in the absence of the relative sequence for comparison, the recitation of specific residues is indefinite.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject

matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

It is noted that the claimed methods lack written description in the priority documents. As such, the claimed invention lacks priority to 1996.

Claims 1, 6, 7, 10 , 39 and 40 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Griffin et al, U.S. Patent No. 5,679,639, issued October 21, 1997, filed August 22, 1994 with full priority to November 18, 1991.

Griffin et al teach antibodies that bind the blood coagulation factor serine proteases and Factor IXa in particular that are capable of inhibiting coagulation (see abstract and column 16, lines 49-51). Griffin et al teach that the antibodies are useful in methods of inhibiting coagulation in a patient by administering antibodies of the invention (column 3, lines 4-9). Griffin et al teach that the present invention provides for a method of inhibiting coagulation in a patient comprising administering to the patient a therapeutically effective amount of a composition comprising a coagulation inhibitor of the invention that includes monoclonal antibodies against factor IXa (column 13, lines 32-40). Griffin et al teach that typical clinical setting for in vivo inhibition of coagulation is when a patient exhibits disseminated intravascualr coagulation (DIC), septic shock, venous or arterial thrombosis (i.e. stroke) and the like conditions requiring anticoagulant intervention (column 29). Therefore, the teachings of Griffin et al anticipate the instantly claimed method of administering and anti-coagulation factor IX/IXa

monoclonal antibody to a patient. Inhibition of coagulation, necessarily provides for inhibition of thrombosis and Griffin et al teaches administration of the anti-coagulation factor IXa monoclonal antibody to the same patient populations claimed herein. Inhibition of coagulation in vivo, necessarily inhibits thrombosis because coagulation is a necessary an inherent component of thrombosis because without coagulation one does not get thrombosis (i.e. coagulation necessarily generates the formation of a thrombus). As such, the methods and inhibitory monoclonal antibody taught by Griffin et al anticipate the instantly claimed invention.

Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al, U.S. Patent No. 5,679,639, issued October 21, 1997, filed August 22, 1994 with full priority to November 18, 1991 in view of Cheung et al (Thrombosis Research, 81(1):65-73, 1996).

Griffin et al is set forth supra. Griffin et al differs by not teaching a monoclonal antibody that binds residues 3-11 of the gla domain of Factor IX and has a affinity of at least 4 nM.

Cheung et al teaches monoclonal antibodies that bind an epitope that includes residues of the amino terminal region of the Gla domain of Factor IX.

It would have been prima facie obvious to substitute the monoclonal antibody of Cheung et al in the method of inhibiting coagulation in a patient of Griffin et al because Griffin et al teaches that monoclonal antibodies that bind serine proteases of the intrinsic pathway of coagulation are useful in methods that inhibit coagulation in a patient.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645